

EDWARD J. MARKEY
7TH DISTRICT, MASSACHUSETTS

ENERGY AND COMMERCE COMMITTEE

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TELECOMMUNICATIONS AND
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RESOURCES COMMITTEE

Congress of the United States
House of Representatives
Washington, DC 20515-2107

2108 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-2107
(202) 225-2836

DISTRICT OFFICES:

5 HIGH STREET, SUITE 101
MEDFORD, MA 02155
(781) 396-2900

188 CONCORD STREET, SUITE 102
FRAMINGHAM, MA 01702
(508) 875-2900
www.house.gov/markey

January 18, 2005

Secretary Tommy G. Thompson
The U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Mr. Secretary:

I am writing to follow up on the December 14, 2004 letter HHS Assistant Secretary Simonson sent in response to my April 7, 2004 inquiry to the President on the status of the potassium iodide program as outlined in Section 127 of the Public Health and Bioterrorism Preparedness and Response Act of 2002 (see enclosed). I do not find the Department's response satisfactory, and in some places it appears to reflect a fundamental misunderstanding of the purpose and intent Congress had when it enacted this bipartisan legislation.

Numerous medical experts support the distribution and use of potassium iodide in the event of a terrorist attack or accident at a nuclear power plant because radioactive iodine could be released as a result of a nuclear incident. It is well known that iodine is taken up by the thyroid. Exposure to radioactive iodine is linked to higher risks of thyroid cancer and other thyroid disorders and disproportionately affects fetuses, infants and children. The medical experts who have endorsed the use of potassium iodide include but are not limited to the American Academy of Pediatrics, American Thyroid Association, and the World Health Organization. Moreover, a National Academy of Sciences study conducted by a panel of experts that included individuals from radiology, thyroid physiology, pharmacology, endocrinology, public health and public safety, mandated by Section 127, came to the same conclusion and based their recommendation on the following findings:

1. Above all, medical experts have found potassium iodide safe. In 2001 the Food and Drug Administration reaffirmed its initial finding in 1978 that potassium iodide is safe and effective.
2. Potassium iodide is highly effective.
3. Potassium iodide is cost effective.

In spite of the overwhelming support of scientific and health experts for the use of potassium iodide, the Departments December 14, 2004 response to my letter states:

While HHS is committed to fulfilling the requirements of Section 127, I [Stewart Simonson, Assist. Secretary] am concerned that the expansion from 10 to 20 miles for use of potassium iodide suggests that the use of potassium iodide is a more effective strategy against

radioactive iodine exposure than science supports. Potassium iodine does not provide general protection from radiation. As we implement Section 127, it is important that we do nothing to indicate that potassium iodine is a surrogate for avoidance, evacuation, and decontamination.

As the author of the amendment that became Section 127 of the Act, I can assure you that at no time have I advocated the use of potassium iodide in lieu of evacuation or any other safety precautions. The legislative history of the provision further indicates that the Congress, in enacting this amendment, made no such determination. The medical experts that I and other proponents of this legislation consulted with during our deliberations on the legislation always suggested that KI be distributed to the public as part of an emergency preparation effort that encompassed evacuation or sheltering. The National Academy of Sciences study mandated by the law also discussed potassium iodide in the same context. Yet, despite all of this, the Department's letter seems to characterize potassium iodide as such a surrogate or alternative to evacuation or sheltering.

I would note that the NAS study clearly concluded:

In the United States and internationally, iodine blockade is supplemental to evacuation and sheltering in place, and this is appropriate. Because KI is most effective when taken within a few hours of exposure to radioiodine, predistribution programs are used extensively.

The short half-life of radioactive iodine-131 leads to high doses of exposure to gamma radiation even during evacuation—one of the main scientific reasons why potassium iodide is effective as a supplement to evacuation. The Department's characterization of potassium iodide as an alternative to additional safety precautions such as evacuation is therefore surprisingly ill-informed and can only serve to deter state and local stakeholders from participating in a program which is supported by preeminent thyroid and health experts.

On December 14, 2004, I sent extensive comments on the statutorily required HHS draft guidelines on the federal Potassium Iodide Stockpiling, Distribution and Utilization program. My staff has received word since that time that the guidelines will be revised and open for further comment. While HHS is revising the guidelines I urge the Department to conform to Section 127 of the law, which includes the expansion of the radius from 10 to 20 miles from nuclear power plants for the distribution of potassium iodide. In addition I would strongly urge that HHS personnel contact appropriate health experts in order to familiarize themselves with the accepted scientific conclusions regarding the utility, efficacy and proper use of potassium iodide.

Thank you for your attention to this matter.

Sincerely,


Edward J. Markey